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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,963	05/21/2002	Wen Yang Wu	150070.401USPC	6047

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,963	WU ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/12 & 8/15/02; 1/13/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see dates above*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

No claims have been cancelled and no preliminary amendments filed as of the date of the instant Office action. Three (3) Information Disclosure Statements (IDSs) filed March 12, 2002, August 15, 2002 and January 13, 2003 have been received with all cited references and made of record.

Claims **1-31** remain in the case.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims **30 and 31** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd. App. ,1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

The disclosure is objected to because of the following informalities:

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

Appropriate correction is required.

Claims **1-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The the written description of the invention within the disclosure is incomplete because the complete chemical identities of most of the specific exemplifications are not completely defined; see NMR/Mass Spec tables wherein compounds are identified by number only. The incomplete spectroscopic data supplied (mass spectral "M^+" data and some NMR data) does not overcome this problem.

Claims **1-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed exemplifications.

The scope of the instant claims as defined by claims **1-4, 12 and 23-29** is excessive because said claims encompass a subject matter area much greater than that supportable by the instant disclosure. This is due in part to the presence in the claims of incompletely defined and therefore open ended generic terms; e.g. at lines 4-5 wherein the terms "optionally substituted" fails to be supported by definitions identifying the "substituents," and "heterocyclic radical" wherein the quantity(ies) and identity(ies) of heteroatom(s) are not provided in the claim, etc. See also the definition of "Ar."

Claims **1-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The subject matter breadth of claims **1-4, 12 and 23-29** is overly broad for the reasons noted in the rejection for excessive scope above.

B. The nature of the invention is directed to O-substituted aldoximes and ketoximes as defined in claims **1-24**, pharmaceutical compositions thereof and methods of treating or preventing rhinoviral infections in mammals.

C. The state of the prior art is well defined by the voluminous disclosure provided by applicant and supplemented by examiner as reported on the PTO-1449 and PTO-892 forms, and does include some anticipatory subject matter which appears to read on the most broadly defined claims (see art rejections below).

D. The level of one or ordinary skill must be relatively high because the instant claims require competence in order to execute the organic synthesis of complex multifunctional molecules and also knowledge of how to safely and effectively administer said compounds to a host in need thereof.

E. The level of predictability in the art is low because the knowledge of the ordinary practitioner does not extend to accurate predictions of what particular molecular structure(s) will represent an effective agent(s) against any particular strain of rhinovirus *in vivo*, i.e. the art is still within the cut and try stage of development.

F. The amount of direction provided by the inventor is limited to a partial disclosure of the specific embodiments prepared, a showing of how to make pharmaceutical compositions, a showing of how to inhibit rhinoviral strains *in vitro* with a substantial number of specific embodiments, but with no showing that the administration of any instant compound will "prevent" rhinoviral infection or development of said infection into disease in a mammalian host.

G. The existence of working examples is limited to the description of a few synthetic examples and a substantial number of biological testing examples. However, the latter examples are not complete because the identity of specific compounds is frequently unavailable because of incomplete identification of compounds synthesized as reported by the disclosure.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is therefore deemed to be excessive because the disclosure is incomplete in its identification of compounds prepared, and because the disclosure does not provide any factual basis in support of the allegation that compounds disclosed

herein are effective to "prevent" infection or development of said infection into disease following exposure to a source of rhinovirus.

Claims **1, 3, 17-22, 27-28 and 30** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** the terms "optionally substituted" (lines 4-5 and definition of "Ar") and "heterocyclic radical" (lines 4-5) are indefinite because the optional substituents have not been defined in the claim and because the quantity(ies) and identity(ies) of heteroatom(s) have not been identified in the claim. See also claims **27, 28 and 30**.

In claim **3**, the term "Y is as defined above" renders the claim incomplete because "Y" is not defined in claim **1** (but is defined in claim **2**).

In claim **10** the term "alkylene" appears to be technically incorrect in view of the dictionary definition in the McGraw-Hill Dictionary of Chemistry (1997, p. 14) which definition requires that the noted term be a monoradical of an alkene. Examiner suggests substitution of the term -- alkyl diradical -- for the noted term. See also claims **1** (2x), **17-21, 27** (2x), **28** (2x) **and 30** (2x).

Claim **22** is incomplete because it does not completely define the subject matter being claimed within the claim. Applicant is respectfully requested to substitute reference to the disclosure with a complete recitation of the subject matter being referred to within the noted claim. Note that the question of completeness of the "Table" incorporated subject matter has been raised in other rejections supra.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **1, 3-4, 8, 10-16, 23-27 and 30-31** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Stetter et al. '416** (PTO-1449 ref. **AA**).

Applicant is referred to the instant document wherein the compounds disclosed read on the instant noted claims including those directed to compounds, pharmaceutical compositions and "use" as a fungicide on plants.

PTO-1449 reference "**AK**" (Bayer AG '906) appears to be an equivalent of the cited **AA** reference. PTO-1449 reference **AK3** (Bayer AG '253) appears to anticipate only the compound and composition claims.

Claims **2, 5-7, 9, 17-22, 28 and 29** would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

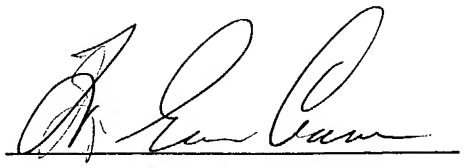
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
05/05/2004



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